2018 Current Fiscal Year Report: Arthritis Advisory Committee

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1. Department or Agency	2. Fiscal Year
Department of Health and Human Services	2018

3. Committee or Subcommittee	3b. GSA Committee No.
Arthritis Advisory Committee	223

4. Is this New During Fiscal Year?	5. Current Charter	6. Expected Renewal Date	7. Expected Term Date
No	04/05/2018	04/05/2020	

8a. Was Terminated During FiscalYear?	8b. Specific Termination Authority	8c. Actual Term Date
No		

9. Agency Recommendation for Next FiscalYear	10a. Legislation Req to Terminate?	10b. Legislation Pending?
Continue	Not Applicable	Not Applicable

11. Establishment Authority Authorized by Law

12. Specific Establishment Authority	13. Effective Date	14. Commitee Type	14c. Presidential?
21 U.S.C. 394	11/28/1990	Continuing	No

15. Description of Committee Scientific Technical Program Advisory Board

16a. Total Number of Reports No Reports for this FiscalYear

17a. Open 2 **17b. Closed** 0 **17c. Partially Closed** 0 **Other Activities** 0 **17d. Total** 2

Meetings and Dates

Purpose	Start	End
The committee discussed the new drug application (NDA) 207924, for baricitinib tablets, submitted by Eli Lilly and Company, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. The discussion included the following: efficacy, safety, including the risk of thromboembolic adverse events, dose selection, and overall risk benefit considerations.	04/23/2018	04/23/2018
The committee met jointly with the Drug Safety and Risk Management Advisory Committee to discuss supplemental new drug application (sNDA) 20998 for CELEBREX (celecoxib) capsules submitted by Pfizer, Inc., which includes the results from the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen Or Naproxen) trial, a cardiovascular outcomes randomized controlled trial that compared celecoxib to ibuprofen and naproxen, and determine whether the findings of the trial change FDA's current understanding of the safety of these three NSAIDs. In order to interpret some of the PRECISION findings, the committees also considered the clinical implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease.	04/24/2018	04/25/2018

Number of Committee Meetings Listed: 2

	Current FY	Next FY
18a(1). Personnel Pmts to Non-Federal Members	$3,667.00	$10,937.00
18a(2). Personnel Pmts to Federal Members	$0.00	$2,187.00

18a(3). Personnel Pmts to Federal Staff	$166,969.00	$166,730.00
18a(4). Personnel Pmts to Non-Member Consultants	$9,553.00	$8,750.00
18b(1). Travel and Per Diem to Non-Federal Members	$4,228.00	$9,420.00
18b(2). Travel and Per Diem to Federal Members	$1,604.00	$6,440.00
18b(3). Travel and Per Diem to Federal Staff	$0.00	$0.00
18b(4). Travel and Per Diem to Non-member Consultants	$14,928.00	$9,594.00
18c. Other(rents,user charges, graphics, printing, mail, etc.)	$46,214.00	$44,694.00
18d. Total	$247,163.00	$258,752.00
19. Federal Staff Support Years (FTE)	1.10	1.10

20a. How does the Committee accomplish its purpose?

The Committee reviews and evaluates data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs.

20b. How does the Committee balance its membership?

Members are experts in arthritis, rheumatology, pediatrics, immunology, allergy, epidemiology, clinical pharmacology, biostatistics, and related specialties. The committee also includes a technically qualified voting member identified with consumer interests. The Committee may include one non-voting member identified with industry interests.

20c. How frequent and relevant are the Committee Meetings?

The committee met two times in FY-18. On April 23, 2018, the committee discussed the new drug application (NDA) 207924, for baricitinib tablets, submitted by Eli Lilly and Company, for the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. The discussion included the following: efficacy, safety, including the risk of thromboembolic adverse events, dose selection, and overall risk benefit considerations. The majority of the committee (10 to 5) voted “No”, that the benefit-risk profile is not adequate to support approval of baricitinib 4 mg once daily for the proposed indication of the treatment of adult patients with moderately to severely active rheumatoid arthritis who have had an inadequate response or are intolerant to methotrexate. These members noted that safety was their main concern, and that more controlled data (potentially another randomized trial) are needed to understand the safety signal and determine whether the thromboembolic events seen in the trials were caused by baricitinib. The members who voted “Yes” indicated that they want refractory patients to have more options, and also noted that more data is warranted. Agency Action: The Agency is currently reviewing all recommendations made during the meeting. On April 24-25, 2018,

the Arthritis Advisory Committee met jointly with the Drug Safety and Risk Management Advisory Committee to discuss supplemental new drug application (sNDA) 20998 for CELEBREX (celecoxib) capsules submitted by Pfizer, Inc., which includes the results from the PRECISION (Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen Or Naproxen) trial, a cardiovascular outcomes randomized controlled trial that compared celecoxib to ibuprofen and naproxen, and determine whether the findings of the trial change FDA's current understanding of the safety of these three NSAIDs. In order to interpret some of the PRECISION findings, the committees also considered the clinical implications of the drug interactions between each of these three NSAIDs and aspirin in patients taking aspirin for secondary prevention of cardiovascular disease. The majority of the committee (12 members) agreed that the Drug Facts label should include a warning regarding the interaction between aspirin and naproxen. These members mentioned the need for consistency between the OTC Drug Facts label of naproxen and that of ibuprofen. The majority of the committee members (17 members) also agreed that there should be no change to the current ibuprofen Drug Facts label. These members noted that there was no new information or data presented to warrant a change to the current label. Agency Action: The Agency is currently reviewing all recommendations that were made during the meeting. It is expected that this committee will meet two to four times in FY-19.

20d. Why can't the advice or information this committee provides be obtained elsewhere?

The committee members are selected from academia, research and clinical practice. The Agency uses the committee recommendations to make the most impartial and broad decisions possible regarding approval of products, indications and labeling. The alternative means of obtaining this advice would involve the recruitment of large numbers of scientist on a full-time basis at maximum rates of compensation.

20e. Why is it necessary to close and/or partially closed committee meetings?

The committee held no closed meetings during FY-18.

21. Remarks

The committee is not required to do any reporting for FY-18.

Designated Federal Officer

Yinghua S Wang DFO

Committee Members	Start	End	Occupation	Member Designation

Becker, Mara	10/01/2015	09/30/2019	Associate Professor of Pediatrics University of Missouri-Kansas City Director, Division of Pediatric Rheumatology Children's Mercy Kansas City	Special Government Employee (SGE) Member
Chung, James	04/13/2016	10/31/2019	Executive Medical Director, US Medical Organization; Inflammation Therapeutic Area Head, Amgen, Inc.	Representative Member
Curtis, Jeffrey	10/01/2015	09/30/2019	William J. Koopman Endowed Professor in Rheumatology and Immunology University of Alabama at Birmingham (UAB) Division of Clinical Immunology and Rheumatology Director, UAB Arthritis Clinical Intervention Program Co-Director, UAB Center for Education and	Special Government Employee (SGE) Member
Davis, John	10/01/2017	09/30/2021	Practice Chair and Vice Chair, Division of Rhematology, Associate Professor of Medicine, Mayo Clinic College of Medicine and Science	Special Government Employee (SGE) Member
Fischer, Aryeh	10/01/2017	09/30/2021	Associate Professor of Medicine, Director Autoimmune and Fibrotic Lung Disease Treatment Program, Center for Lungs and Breathing, University of Colorado School of Medicine	Special Government Employee (SGE) Member
Horonjeff, Jennifer	12/30/2015	09/30/2019	CONSUMER REPRESENTATIVE; Research Fellow & Patient Advocate, Center for Immune Disease with Onset in Childhood	Special Government Employee (SGE) Member
Oliver, Alyce	10/01/2016	09/30/2020	Professor of Medicine, Medical College of Georgia, Augusta University	Special Government Employee (SGE) Member
Ranganath, Veena	10/01/2015	09/30/2019	Associate Clinical Professor Division of Rheumatology David Geffen School of Medicine at UCLA	Special Government Employee (SGE) Member
Richards, John	10/01/2017	09/30/2021	Chief, Division of Rheumatology Veterans Affairs Pittsburgh Healthcare System, Clinical Associate Professor of Medicine, University of Pittsburgh	Regular Government Employee (RGE) Member
Scher, Jose	10/01/2016	09/30/2020	Assistant Professor in Medicine and Rheumatology, New York University School of Medicine	Special Government Employee (SGE) Member
Solomon, Daniel	06/27/2016	09/30/2020	Professor of Medicine Harvard Medical School, Chief, Section of Clinical Sciences Division of Rheumatology Division of Pharmacoepidemiology Brigham and Women's Hospital	Special Government Employee (SGE) Member
Tchetgen Tchetgen, Eric	10/01/2014	09/30/2018	Associate Professor of Biostatistics and Epidemiologic Methods, Harvard School of Public Health	Special Government Employee (SGE) Member

Number of Committee Members Listed: 12

Narrative Description

FDA's strategic priorities in responding to the public health challenges of the 21st century are to advance regulatory science and innovation; strengthen the safety and integrity of the global supply chain; strengthen compliance and enforcement activities to support

public health; expand efforts to meet the needs of special populations; advance medical countermeasures and emergency preparedness; advance food safety and nutrition; promote public health by advancing the safety and effectiveness of medical products; establish an effective tobacco regulation, prevention, and control program; and manage for organizational excellence and accountability. The Arthritis Advisory Committee supports FDA's strategic priorities by reviewing and evaluating available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of arthritis, rheumatism, and related diseases, and makes appropriate recommendations to the Commissioner of Food and Drugs. This supports the development of safe and effective new medical technologies, and advances the status of the Agency as a science-based and science-led regulatory agency, providing global leadership in the protection of public health.

What are the most significant program outcomes associated with this committee?

	Checked if Applies
Improvements to health or safety	✓
Trust in government	✓
Major policy changes	✓
Advance in scientific research	✓
Effective grant making	
Improved service delivery	
Increased customer satisfaction	✓
Implementation of laws or regulatory requirements	✓
Other	

Outcome Comments

N/A

What are the cost savings associated with this committee?

	Checked if Applies
None	
Unable to Determine	✓
Under $100,000	
$100,000 - $500,000	
$500,001 - $1,000,000	
$1,000,001 - $5,000,000	
$5,000,001 - $10,000,000	
Over $10,000,000	
Cost Savings Other	

Cost Savings Comments

The utilization of the Arthritis Advisory Committee enables the Agency to obtain required and frequently scarce professional services from medical and scientific experts not otherwise available to the Agency; and to obtain the services of these experts not otherwise available to the Agency; and to obtain the services of these experts only on an as needed bases rather than on a full time basis. The service of the committee resulted in advice for the improvement of the public health, for which it is difficult to assign a financial value.

What is the approximate Number of recommendations produced by this committee for the life of the committee?

36

Number of Recommendations Comments

The committee made 36 recommendations from FY-03 through FY-18 - see question 20a of the annual report for specific accomplishments.

What is the approximate Percentage of these recommendations that have been or will be Fully implemented by the agency?

78%

% of Recommendations Fully Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and therefore, the Agency has the option of not implementing the advice.

What is the approximate Percentage of these recommendations that have been or will be Partially implemented by the agency?

8%

% of Recommendations Partially Implemented Comments

The function of an advisory committee is purely advisory in nature. Although the FDA most often accepts the recommendations from its committees, the advice is purely advisory in nature, and the Agency has the option of not implementing the advice.

Does the agency provide the committee with feedback regarding actions taken to implement recommendations or advice offered?

Yes ☑ No ☐ Not Applicable ☐

Agency Feedback Comments

It usually does. Product approval issues are first released to the sponsor. When appropriate, information is made available to the public. Actions related to guidance documents or other general matters issues are available publicly when implemented.

What other actions has the agency taken as a result of the committee's advice or recommendation?

	Checked if Applies
Reorganized Priorities	☑
Reallocated resources	☐
Issued new regulation	☑
Proposed legislation	☐
Approved grants or other payments	☐
Other	☑

Action Comments

FDA approves or chooses not to approve new medical products.

Is the Committee engaged in the review of applications for grants?

No

Grant Review Comments

N/A

How is access provided to the information for the Committee's documentation?

	Checked if Applies
Contact DFO	☑
Online Agency Web Site	☑
Online Committee Web Site	☑
Online GSA FACA Web Site	☑
Publications	☑
Other	☐

Access Comments

N/A